

Saponin Adjuvant

Pat. No. 5,057,540

Applicant Kensil and Marciani

The following have been received by the US Patent and Trademark Office on the date

Serial No. \_\_\_\_\_  
\_\_\_\_\_ pages (\_\_\_\_ Design)  
Specification  
Claims (# of claims - \_\_\_\_\_)  
Abstract  
Drawings; Figs. \_\_\_\_\_  
Informal  
Application Cover Sheet  
Declaration / Power of Attorney (\_\_\_\_ Unsigned)  
Statement Claiming Small Entity Status  
Copy of Notice to File Missing Parts  
Request for filing CPA; 37 CFR 53(d)  
IDS, PTO-1449, and \_\_\_\_\_ references (Supp. \_\_\_\_\_)

☒ Certificate of Mailing under 37 CFR 1.8(a)  
☐ Response to Office Action/Restriction Req.  
☐ Petition for \_\_\_\_\_ month extension of time  
☐ Assignment and Cover Sheet  
☐ Amendment (☐ Preliminary; ☐ After Final)  
☐ Notice of Appeal  
☐ Appellant's Brief (triplicate) (☐ Reply Brief)  
☐ Letter to Chief Draftsperson  
☐ Issue Fee / ☐ Maintenance Fee Transmittal  
☐ Sequence listing; ☐ Diskette  
☐ Transmittal Letter  
☐ Check for \$ \_\_\_\_\_; check # \_\_\_\_\_  
☒ Deposit Account Authorization \$ 100.00

Request for Cert. of Correction, Cert. of Correction &  
Copy of Vydac HPLC Columns and Packing Materials catalog  
2/23/99 Docket No. 106941.141 Atty/paralegal/secy: HLB/CS/KK

Saponin Adjuvant

Title:

Pat. No. 5,057,540

Applicant Kensil and Marciani

In the above matter, the following have been received by the US Patent and Trademark Office on the date stamped hereon.

☐ Express Mail Label No. \_\_\_\_\_  
☐ Application incl. \_\_\_\_\_ pages (\_\_\_\_ Design)  
\_\_\_\_\_ pp. of specification  
\_\_\_\_\_ pp. of claims (# of claims \_\_\_\_\_)  
\_\_\_\_\_ pp. of abstract  
\_\_\_\_\_ sheets of drawings; Figs. \_\_\_\_\_  
☐ formal ☐ informal  
☐ Provisional Application Cover Sheet  
☐ Declaration / Power of Attorney (\_\_\_\_ Unsigned)  
☐ Verified Statement Claiming Small Entity Status  
☐ Copy of Notice to File Missing Parts  
☐ Request for filing CPA; 37 CFR 53(d)  
☐ IDS, PTO-1449, and \_\_\_\_\_ references (Supp. \_\_\_\_\_)

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☐ Check for \$ \_\_\_\_\_; check # \_\_\_\_\_  
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☒ other: Request for Cert. of Correction, Cert. of Correction &  
☐ other: Copy of Vydac HPLC Columns and Packing Materials catalog

Mailing Date: 2/23/99 Docket No. 106941.141 Atty/paralegal/secy: HLB/CS/KK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 5,057,540  
Issued: October 15, 1991  
In the Name of: Charlotte A. Kensil and Dante J. Marciani  
For: Saponin Adjuvant  
Docket No.: 106941.141

TRANSMITTAL LETTER

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington D.C. 20231.

on Feb. 23, 1999  
(Date of Deposit)  
Karen Kenney  
Person Making Deposit  
Km [Signature]  
Signature

The following documents are submitted for filing:

1. Request for a Certificate of Correction Under 37 C.F.R. § 1.323;
2. A copy of the April, 1985 "VYDAC HPLC COLUMNS AND PACKING MATERIALS" catalog from The Separations Group;
3. Certificate of Correction; and
4. Return Postcard.

The Commissioner is authorized to debit the fee set forth in 37 C.F.R. § 1.20(a) of \$100.00 from Deposit Account No. 08-0219. No other fee is believed to be due, however, if one is required, the Commissioner is authorized to debit such fee from Deposit Account No. 08-0219.

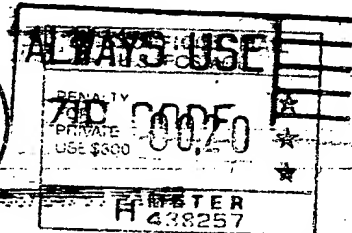
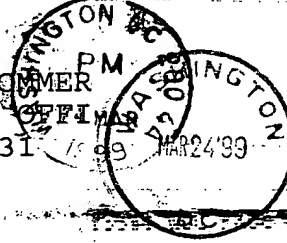
Dated: February 23, 1999

Hale and Dorr LLP  
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(617) 526-6000

Respectfully submitted,

Colleen Superko  
Colleen Superko  
Registration No. 39,850

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231



A request for a Certificate of Correction has  
been received for U.S. Patent 5057540

COLLEEN SUPERKO  
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BOSTON, MA 02109

106941.141  
AQLA-2



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 5,057,540  
Issued: October 15, 1991  
In the Name of: Charlotte A. Kensil and Dante J. Marciani  
For: Saponin Adjuvant  
Docket No.: 106941.141

**REQUEST FOR A CERTIFICATE OF CORRECTION**  
**UNDER 37 C.F.R. § 1.323**

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

The attached Certificate of Correction is made under 37 C.F.R. § 1.323 and is respectfully requested to be issued under 35 U.S.C. § 255.

In this Request for a Certificate of Correction, it shows that mistakes occurred in good faith and do not involve such changes in the patent as would either constitute new matter or would require reexamination.

The Commissioner is authorized to debit the fee set forth in 37 C.F.R. § 1.20(a) of \$100.00 from Deposit Account No. 08-0219. No other fee is believed to be due, however, if one is required, the Commissioner is authorized to debit such fee from Deposit Account No. 08-0219.

This Request for a Certificate of Correction is to correct the pore size for the Vydac C<sub>4</sub> columns to 300 Å and to correct the pseudo-molecular ion mass of QA-21 to 1988.

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington D.C. 20231.

on Feb. 23, 1999  
(Date of Deposit)

Karen Kenney  
Person Making Deposit

[Signature]  
Signature

U.S. Patent No. 5,057,540  
Request for a Certificate of Correction

This request is being made for the following reasons:

The Vydac C<sub>4</sub> columns referenced in the specification and in the claims are commercially available reverse phase high pressure liquid chromatography ("HPLC") columns from The Separations Group, Hesperia, California. In addition, "Vydac" is a trademark of The Separations Group.

To support this Request for a Certificate of Correction, attached is a copy of the "VYDAC HPLC COLUMNS AND PACKING MATERIALS" catalog from The Separations Group, dated April, 1985. The catalog lists the complete line of HPLC columns that were commercially available at the time the underlying patent application was filed. On page 1 of the catalog is an index identifying the Vydac C<sub>4</sub> reverse phase HPLC columns as product "214 TP: Wide pore C<sub>4</sub> Reverse Phase" and indicating pages 8-9 of the catalog for a description. On page 8 of the catalog, the Vydac C<sub>4</sub> column is described as "[a] large pore (300 Å) spheroidal column packing material - ideal for large biomolecules - with an endcapped C-4 reverse phase." On page 9 of the catalog, the table shows that there are eleven different columns sold as Vydac C<sub>4</sub> columns, all with the same 300 Å pore size, but with different particle sizes, different column interior diameters ("i.d."), and different lengths.

There are two different kinds of Vydac C<sub>4</sub> columns referenced in the instant specification and one kind of Vydac C<sub>4</sub> column referenced in the claims. In the specification, a preparative Vydac C<sub>4</sub> column has a 5 μm particle size, 10 mm column i.d.

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Request for a Certificate of Correction

and 25 cm length. An analytical Vydac C<sub>4</sub> column having a 5  $\mu$ m particle size, 4.6 mm column i.d., and 25 cm length is the second type described in the specification. In the claims, reference is made only to the analytical Vydac C<sub>4</sub> column, that is a Vydac C<sub>4</sub> column having 5  $\mu$ m particle size, 4.6 mm column i.d., and 25 cm length.

Thus, it is clear that any Vydac C<sub>4</sub> column always has a 300 Å pore size. For identification purposes, then, the patent could have simply listed the Vydac C<sub>4</sub> columns as a 5  $\mu$ m particle size, 4.6 mm column i.d. (or 10 mm column i.d.) and 25 cm length. The 300 Å pore size is not a necessary characteristic to be listed as, by definition from the manufacturer, all Vydac C<sub>4</sub> columns have a 300 Å pore size.

In the specification and the claims, all references, except one, as noted below, erroneously give the pore size of the Vydac C<sub>4</sub> columns as 330 Å. As pointed out above, the correct pore size for the Vydac C<sub>4</sub> reverse phase HPLC columns is 300 Å.

The one reference to the correct pore size for the Vydac C<sub>4</sub> column is made in the patent specification at column 16, the sixth line under TABLE 4. Here, the HPLC conditions are provided as "Vydac [C<sub>4</sub>], 5  $\mu$ m particle size, 300 Å pore size, .46 x 25 cm."

Another error occurred with regard to the pseudo-molecular ion mass of QA-21. The specification erroneously refers to the pseudo-molecular ion mass of QA-21 as 1980. The correct pseudo-molecular ion mass for QA-21 is 1988. The correct ion mass of QA-21 is found in the accompanying figures. Figure 8C, which is sheet 16 of 23 in the patent, provides the mass spectroscopy fast action bombardment of QA-21 and indicates,

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Request for a Certificate of Correction

on the far right hand side, that the appropriate pseudo-molecular ion mass of QA-21 is 1988.

Hence, the errors in providing the pore size for the Vydac C<sub>4</sub> column as 300 Å and in providing the pseudo-molecular ion mass of QA-21 as 1980 were typographical errors. The errors were made in the first draft of the patent application, with the exceptions noted, and continued to be made throughout the prosecution of the application. The errors were made in good faith and without deceptive intent. Further, as shown above, correcting the pore size and the pseudo-molecular ion mass mistakes are of minor character that do not involve a change in the patent that would either constitute new matter or would require reexamination.

Although the 300 Å pore size was correctly given with TABLE 4 and the 1988 ion mass was correctly given in Figure 8C, the errors of the incorrect descriptions of a 330 Å pore size and of the 1980 ion mass were not noticed until it was first brought to the attention of the patent assignee in a European Opposition of the corresponding European Patent. The errors were made in good faith and without deceptive intent.

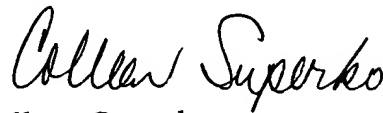
In conclusion, correcting the pore size from 330 Å to 300 Å and the pseudo-molecular mass of QA-21 from 1980 to 1988 are mistakes of minor character, that are not the fault of the Patent and Trademark Office, and a showing has been made that such mistakes occurred in good faith and without deceptive intent. Again, the corrections do

U.S. Patent No. 5,057,540  
Request for a Certificate of Correction

not involve such changes in the patent as would either constitute new matter or would require reexamination.

The Commissioner is therefore respectfully requested to issue the attached Certificate of Correction.

Respectfully submitted,



Colleen Superko  
Registration No. 39,850

Dated: February 23, 1999

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/netuser6/karenb/baker/aquila/106941.141/certcorr.wpf



UNITED STATES PATENT AND TRADEMARK OFFICE  
CERTIFICATE OF CORRECTION

PATENT NO.: 5,057,540  
DATED: October 15, 1991  
INVENTORS: Charlotte A. Kensil and Dante J. Marciani

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 4, line 53, "330 Å" should be -- 300 Å --.  
At column 5, line 66, "330 Å" should be -- 300 Å --.  
At column 6, line 2, "330 Å" should be -- 300 Å --.  
At column 6, line 18, "330 Å" should be -- 300 Å --.  
At column 6, line 22, "330 Å" should be -- 300 Å --.  
At column 6, line 39, "330 Å" should be -- 300 Å --.  
At column 6, line 43, "330 Å" should be -- 300 Å --.  
At column 6, line 59, "330 Å" should be -- 300 Å --.  
At column 6, line 62, "330" should be -- 300 --.  
At column 9, line 43, "330 Å" should be -- 300 Å --.  
At column 10, line 31, "330 Å" should be -- 300 Å --.  
At column 12, line 56, "1980" should be -- 1988 --.  
In claim 1, at column 22, line 63, "330 Å" should be -- 300 Å --.  
In claim 2, at column 23, line 8, "330 Å" should be -- 300 Å --.  
In claim 5, at column 23, line 33, "330 Å" should be -- 300 Å --.  
In claim 8, at column 23, line 59, "330 Å" should be -- 300 Å --.  
In claim 11, at column 24, line 25, "330 Å" should be -- 300 Å --.

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PATENT NO. 5,057,540